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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/680,070 | 10/06/2003 | Keith E. Myers | 816020-100046-US | 9949 |
| 34026 | 7590 | 10/13/2005 | EXAMINER | |
| JONES DAY | | | MILLER, CHERYL L | |
| 555 SOUTH FLOWER STREET FIFTIETH FLOOR | | | ART UNIT | |
| LOS ANGELES, CA 90071 | | | PAPER NUMBER | |

3738

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/680,070

Applicant(s)

MYERS ET AL.

Examiner

Cheryl Miller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 4, 6, 7 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4, 6, 7, 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/4/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1, 3-7, and 9-13 have been considered but are moot in view of the new ground(s) of rejection. It is noted to the applicant that "three elliptical shaped members" is being interpreted to mean three or more, or at least three members.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, 6, 7, and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the ellipse" in lines 5 and 6. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the ellipse" to recite for instance --each ellipse--. Claims 3, 4, 6, 7, and 9-13 depend upon claim 1 and inherit all problems associated with the claim.

Claim 4 recites the limitation "the sinus commissural posts" in line 2. There is insufficient antecedent basis for this limitation in the claim. No sinus commissural posts have been positively claimed in the structure. If applicant is referring to the native posts, it is suggested to insert --native-- before sinus.

Claims 7, 9, and 10 each recite the limitation "said elliptical anchoring structure" in line 1 of each claim. There is insufficient antecedent basis for this limitation in the claims. It is

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suggested to change the above to either --said anchoring structure-- or --said elliptical members--

Claim 11 recites the limitation "the outflow end" in line 2. There is insufficient antecedent basis for this limitation in the claim. It is suggested to change "the outflow end" to recite --the proximal end-- or --the distal end--.

Claim 13 recites the limitation "the sinus commissural posts" in line 2. There is insufficient antecedent basis for this limitation in the claim. No sinus commissural posts have been positively claimed in the structure. If applicant is referring to the native posts, it is suggested to insert --native-- before sinus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Camilli (US 5,607,465). Camilli discloses an assembly (fig.4) comprising a valve (2), a collapsible and expandable anchoring structure (1) having three elliptical shaped elements (6, 5, and 6'), flared at each end (see fig.1, 4) of the ellipse and joined side by side to form junctures (at bends).

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Claims 1, 3, 4, 7, 9, 10, 11, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen et al. (US 6,582,462 B1, cited in IDS). Andersen discloses an assembly (fig.2) comprising a valve (6), a collapsible and expandable anchoring structure (1) having three elliptical shaped elements (see three elliptical shaped elements in attachment 1), flared at each end (flared in fig.8, 9 shown to flare to the shape of the vessel) of the ellipse and joined side by side to form junctures (as seen in attachment 1). Andersen discloses support posts (4) having axial slots (seen in figs).

Claims 1, 3, 7, 9, 10, 11, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Garrison et al. (US 6,425,916 B1, cited in IDS). Garrison discloses an assembly (fig.9) comprising a valve (38 or 6), a collapsible and expandable anchoring structure (8) having three elliptical shaped elements (see three elliptical shaped elements in attachment 2, 3), flared at each end (flared in fig.8, 8, 19, 20) of the ellipse and joined side by side to form junctures (as seen in attachment 2, 3). Garrison discloses support posts having axial slots (see attachment 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorpe et al. (US 2004/0193253 A1, cited previously). Thorpe discloses an assembly (fig.15)

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comprising a valve (leaflets 30, 40, 300, 340), a collapsible and expandable anchoring structure (wire frame [0026]) having a plurality of elliptical shaped elements (two elliptical elements are shown in fig.15; 104+150 and 160+170), flared at each end (see fig) of the ellipse and joined side by side to form junctures (at 180). Thorpe discloses a valve assembly comprising elliptical members, however discloses only two instead of three. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have three members instead of two, since it would have been a mere duplication of parts and both bi-leaflet and tri-leaflet systems are well known in the art. *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960).

Allowable Subject Matter

Claims 6 and 12 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER

Attachment 1 (marked up) #1

U.S. Patent

Jun. 24, 2003

Sheet 1 of 4

US 6,582,462 B1

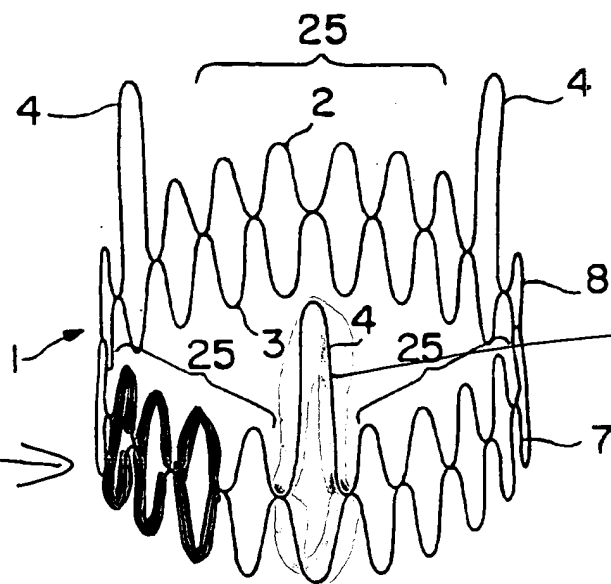


FIG. 1

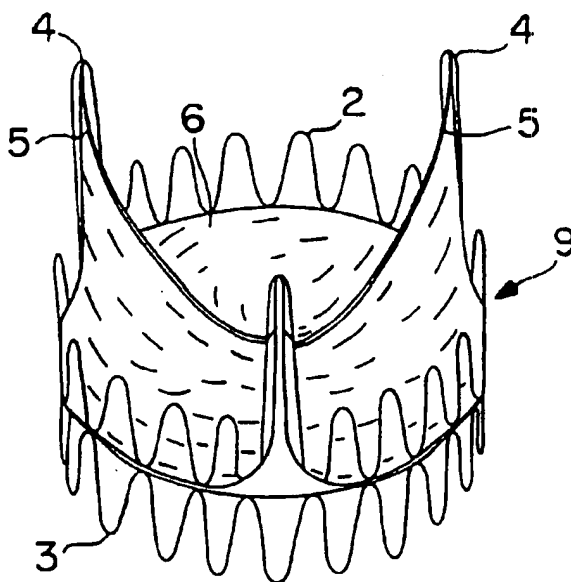


FIG. 2

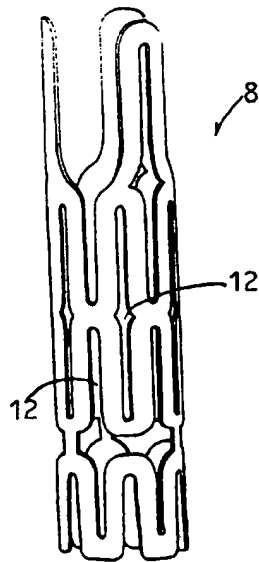


FIG. 7

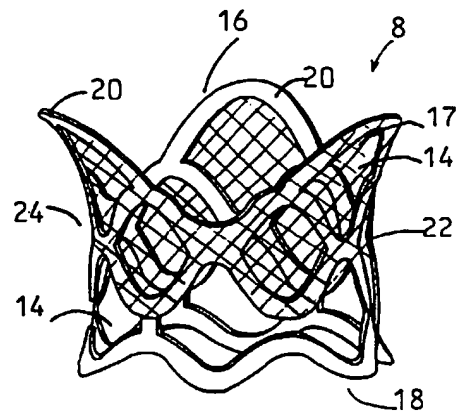


FIG. 8

@ least three
elliptical members
shown in red →

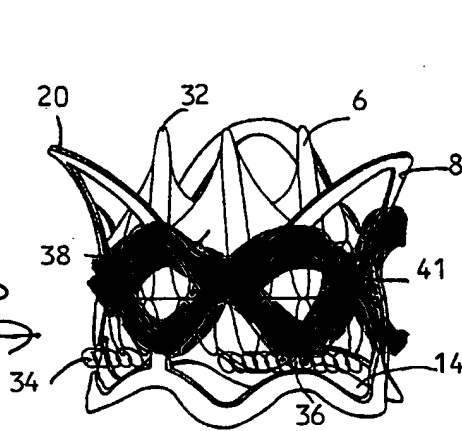


FIG. 9

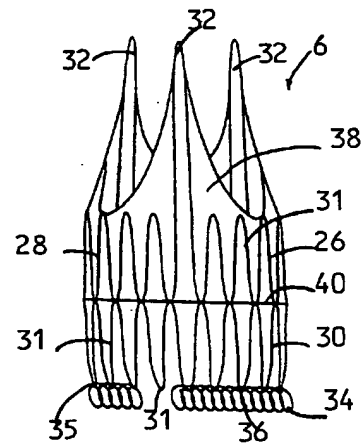


FIG. 10

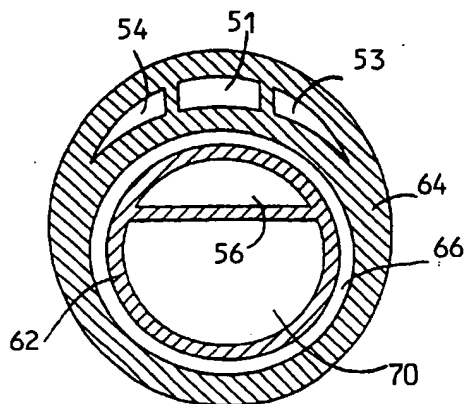


FIG. 12

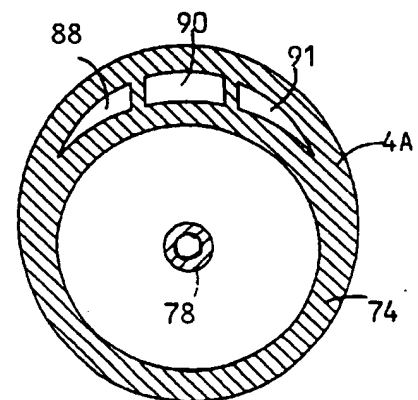


FIG. 15

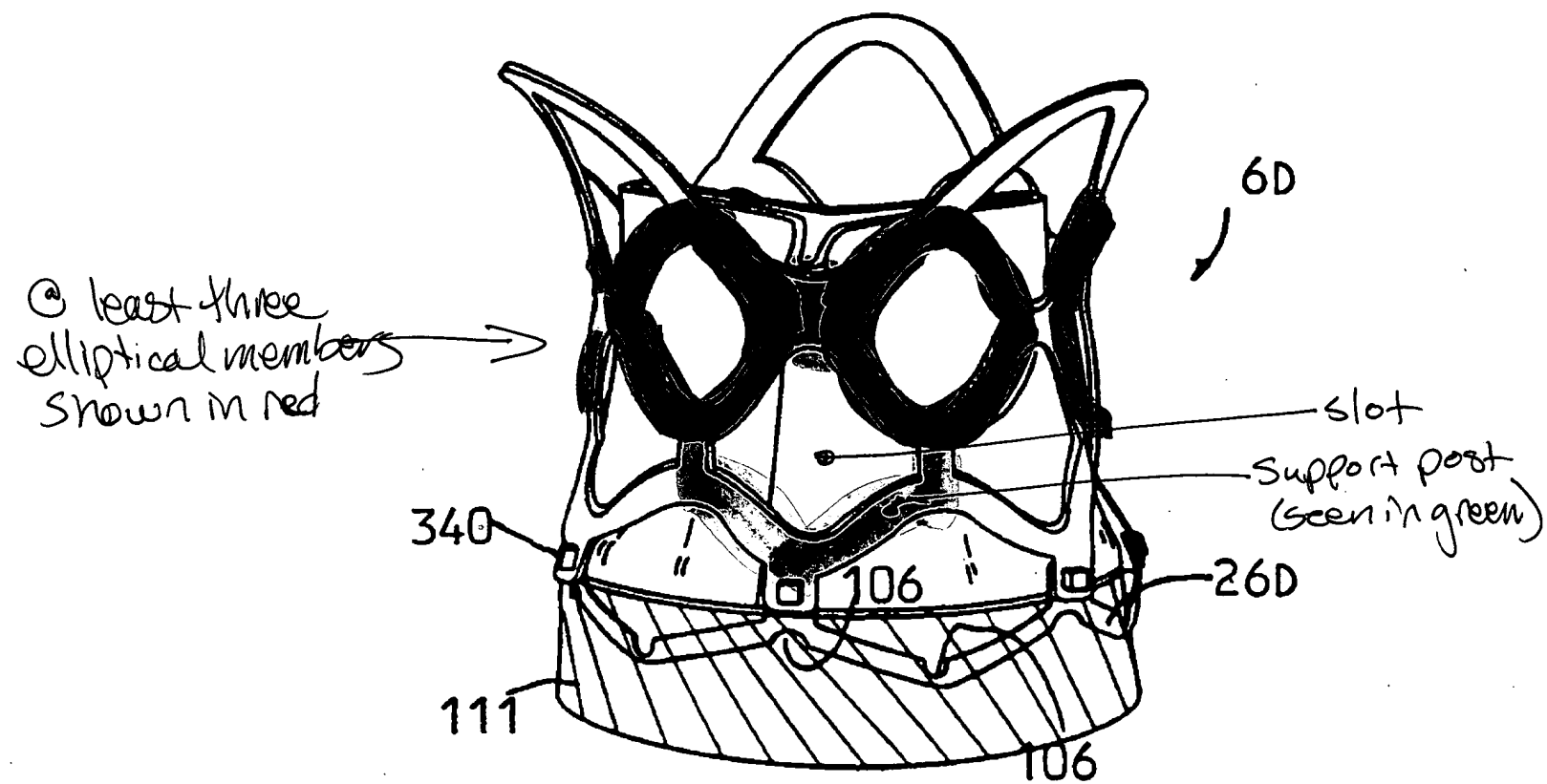


FIG. 38